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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,703	04/19/2006	Olof Wallquist	PL222968APCT	6307
324	7590	01/14/2008		
JoAnn Villamizar Ciba Corporation/Patent Department 540 White Plains Road P.O. Box 2005 Tarrytown, NY 10591			EXAMINER BARKER, MICHAEL P	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 01/14/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/576,703

Applicant(s)

WALLQUIST ET AL.

Examiner

Michael P. Barker

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/29/2007, Amd After Non-Fin. Rej.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-13 and 24 is/are allowed.
- 6) ☒ Claim(s) 1-8, 15 and 23 is/are rejected.
- 7) ☒ Claim(s) 2-7, 14, 15, 23 and 25-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant amended **Claims 1, 8, 9, 14, and 25** and added **Claim 27**. **Claims 1-15 and 23-27** are pending in this Application.

Response to Remarks

Applicant's amendments to **Claims 1, 8, 9, 14, and 25** and addition of **Claim 27** are acknowledged. However, while Applicant's amendment to **Claim 1** overcomes the rejection previously put forth under 35 USC 102(e), it brings about a new rejection under 35 USC 103(a), *infra*.

Claim Rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 15, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIPO Publication No. WO 2004/076457 A1, published 09/10/2004.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Determining the scope and contents of the Prior Art

The '457 publication discloses a process for making DPPs and mixtures of DPPs by reacting a succinate with an aromatic or heteroaromatic nitrile or nitriles. The Specification of the '457 publication discloses that when using two nitriles, a mixture of 0.1 to 1.9M of one nitrile and 1.9 to 0.1M of the other nitrile can be used. Five mixtures of DPP compounds are exemplified in the '457 publication, and each is prepared from a 1:1 mixture of nitriles.

Ascertaining the Differences Between the Prior Art and the Claims at Issue

Applicant's instantly claimed invention discloses a process for making DPPs and mixtures of DPPs by reacting a succinate with an aromatic or heteroaromatic nitrile or nitriles. Regarding the nitrile mixture used in the instant invention, the nitrile of formula 2 is present in a small amount, 1M% to 10M% of total nitrile, which overlaps with the mole ratios found in the '457 publication.

Resolving the Level of Ordinary Skill in the Pertinent Art

The level of ordinary skill in the pharmacological arts is extremely high. Because of the high level of skill and predictability of the pharmacological arts, merely selecting proportions and ranges and modifying the process conditions, such as temperature, reaction time, *and concentration is not a patentable modification absent a showing of criticality. In re Aller*, 220 F.2d, 454, 105 (emphasis added). In this case, Applicant has not argued the slight modification to the mole ratios is critical to the instant invention, or provides unexpected results, or is otherwise patentably distinct from the '457 publication. Applicant's modification of the process

disclosed in the '457 publication is akin to routine optimization and cannot be considered to be an unobvious or novel distinction. Even if Applicant argues the instant process provides better yield (i.e. better overall results in achieving the desired product), these results would not be tantamount to 'unexpected results', since a PHOSITA would know modification of mole ratios within a process often produces better results.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Specifically, **Claim 1** recites the phrase, "wherein the amount of compound 2 is from 1 to 10 mole % based on the total amount of nitrile in the reaction mixture." It is unclear exactly what Applicant has intended by this phraseology. For instance, which nitrile, what is the total amount of nitrile in the mixture, when is compound 2 1 mole %, when is it 2 mole %, when is it 3 mole %, etc. Applicant has not clearly defined nor distinctly pointed out the subject matter sought to be patented in Claim 1, due to the cited phrase.

Objections

Claims 2-8, 14, 15, 23, and 25-27 are objected to for their dependence on a rejected base claim.


Allowable Subject Matter

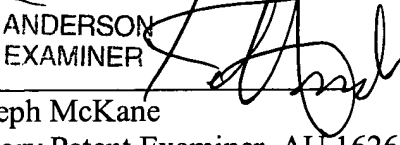
Claims 9-13 and 24 are drawn to allowable subject matter.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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